IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent application of:

Applicant(s):

Raghu Raghavan et al.

Serial No:

10/771,545

Filing Date:

February 5, 2004

Title:

METHOD AND SYSTEM FOR PREDICTION AND MANAGEMENT

OF MATERIAL AND INFORMATION TRANSPORT IN AN

ORGANISM

Examiner:

Dennis Rosario

Art Unit:

2624

Docket No.

SCHWP0212US

APPEAL BRIEF

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The undersigned submits this brief for the Board's consideration of the appeal of the Examiner's decision, mailed December 14, 2007, finally rejecting claims 1-38 and 41 of the above-identified application.

The fee for filing an appeal brief is being paid herewith. In the event any additional fee is due in connection with this paper, the Commissioner is authorized to charge those fees to our Deposit Account No. 18-0988 (under the above Docket-Number). In the event an extension of time is needed to make the filing of this paper timely and no separate petition is attached, please consider this a petition for the requisite extension and charge the fee to our Deposit Account No. 18-0988 (under the above-indicated docket number).

I. Real Party in Interest

The real party in interest in the present appeal is BrainLAB AG.

II. Related Appeals and Interferences

Neither appellant, appellant's legal representative, nor the assignee of the present application are aware of any appeals or interferences which will directly affect, which will be directly affected by, or which will have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-38 and 41 have been finally rejected and claims 39 and 40 have been withdrawn from consideration. The claims on appeal are claims 1-38 and 41, and a correct copy of these claims is reproduced in the Claims Appendix.

IV. Status of Amendments

Claim 41 was amended in a request for reconsideration of the rejections set forth in the final Office Action mailed on December 12, 2007. In an Advisory Action mailed February 28, 2008, the Examiner indicated that for purposes of appeal the amendment to claim 41 would be entered.

V. Summary of Claimed Subject Matter

The following is a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which refers to the specification by page and line number in brackets.

Claim 1

A computer-implemented method of dynamically modeling and displaying a passage of material or information between at least two spatially distributed objects in a body [7/8-20], comprising:

creating a first data set of entities (460) between which material or information is transferred [7/16-8/8; 10/9-11/10];

creating a second data set of channels (467) connecting the entities [11/18-23]; creating a third data set of types of material or information (463) that each entity transfers via each channel [11/11-17];

creating a dynamic map (450) that includes a list of active entities, wherein the dynamic map is communicatively coupled to the active entities so as to provide information thereto [8/20-9/20];

using the dynamic map in conjunction with the first, second, and third data sets to perform a simulation of the transfer of material or information between entities [9/8-20]; and

outputting the simulation results [36/4-13].

Claim 41

A computer program embodied on a computer readable medium for dynamically modeling and displaying a passage of material or information between at least two spatially distributed objects in a body [7/8-20], comprising:

code that creates a first data set of entities (460) between which material or information is transferred [7/16-8/8; 10/9-11/10];

code that creates a second data set of channels (467) connecting the entities

[11/18-11/23];

code that creates a third data set of types of material or information (463) that each entity transfers via each channel [11/11-17];

code that creates a dynamic map (450) that includes a list of active entities, wherein the dynamic map is communicatively coupled to the active entities so as to provide information thereto [8/20-9/20];

code that uses the dynamic map in conjunction with the first, second, and third data sets to perform a simulation of the transfer of material or information between entities [9/8-20]; and

code that outputs the simulation results [36/4-13].

VI. Grounds of Objection/Rejection to Be Reviewed on Appeal

- A. Claims 1-5, 7-11, 13-21, 23-28 and 41 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,305,331 (referred to herein as *Allen*).
- B. Claim 6 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Allen* in view of U.S. Patent No. 6,210,967 (referred to herein as *Bard*).
- C. Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Allen* in view of U.S. Patent No. 6,836,569 (referred to herein as *Le Pennec et al.*).
- D. Claim 22 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Allen* in view of U.S. Patent No. 5,003,497 referred to herein as *Priem*).

VII. Argument

The rejections advanced by the Examiner are improper and should be reversed for at least the following reasons.

A. Background

Cell migration routes are significant for the spread of cancer. If cells from a tumor have migrated and begun to form secondary tumors, the effort and pain of surgery may be wasted. The method in accordance with the present invention, for example, based on known tumor cells, can be used to identify likely metastasis sites in which new tumors are likely. These identified sites then can be closely examined by the radiologist in search of secondary tumors. If such secondary tumors, along with the primary, seem operable, queries specifying the secondary locations can specify sites at risk for tertiary tumors.



Fig. i - A T1-weighted contrast enhanced image

An exemplary use of the method in accordance with the invention may be the presentation of metastasis routes to the physician or radiotherapist. In Fig. i above-left, there is shown a display that is called a T1-weighted contrast-enhanced magnetic resonance image of an axial slice of a human brain with recurrent tumor (axial means horizontal in this context). The dark area within the brain at the top of figure is a resection cavity, meaning that a prior surgery has been performed (e.g., to remove a

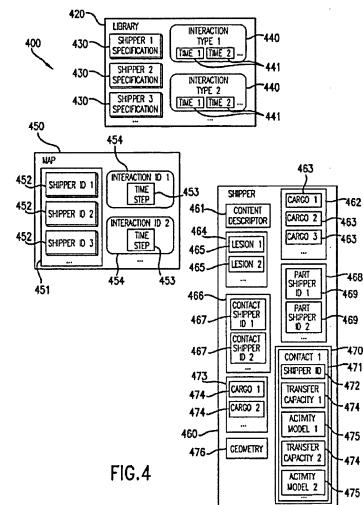
brain tumor) and is now fluid-filled (which appears dark in such an image). The patient was given a contrast agent, the appearance of which in a brain image is often indicative of a brain tumor (though this needs to be confirmed with a biopsy). Thus, Fig. i indicates that the tumor has recurred at the boundaries of the previously resected tumor.

However, the fact that there are no particularly enhanced areas within the tissue region of the brain other than those already identified does not mean that there are no other likely zones of recurrence for the cancer. For example, it is well known that white matter tracts are pathways along which primary brain tumors can spread.

In the context of presenting metastasis routes, the present invention provides a method that enables dynamic predictions of zones of likely recurrence of primary tumors. The predictions may be based on either statistical atlas-based and/or simulation-based methods.

Claim 1 sets forth a computer-implemented method of dynamically modeling and displaying a passage of material or information between at least two spatially distributed objects in a body. Each feature of claim 1 is recited below, and a brief explanation is provided, and reference is made to elements shown in Fig. 4 (reproduced below) where appropriate.

 creating a first data set of entities between which material or information is transferred; The entities, for example, can be referred to as "Shippers", which are a class of user-modifiable objects. Each Shipper 460 contains internal variables comprising the content of material which is to be shipped. The content may be stored as a single number or as a spatial distribution of concentration, or as a total quantity in the whole or a specified part of the space occupied by the shipper.



2) creating a second data set of channels connecting the entities;

The channels, for example, can be contacts 467 (e.g., a list of other Shippers with which a Shipper is in direct contact). Each contact has a transfer capacity 474 for each Cargo that it may carry, and a default activity model 475 for the Shipper's use of this capacity.

 creating a third data set of types of material or information that each entity transfers via each channel; For example, the third data set may be Cargo 463 that is received and/or transmitted by Shippers. Examples of Cargo include nerve signals, hormones, fluids, drugs, etc.

4) creating a dynamic map that includes a list of active entities, wherein the dynamic map is communicatively coupled to the active entities so as to provide information thereto;

The dynamic map, for example, may be a Map 450 that contains a list of active entities (e.g., active Shipper IDs 452). A user or program may select individual Shippers or groups of Shippers to enter in the current Map. When this list changes, it informs each active Shipper of the other active Shippers with which it is in contact. Where a Shipper has options concerning level of detail in its Geometry, the Map can store the current option and update the Shipper when the user or program requests a change. The Map also can store the interaction ID 454 and the current time step 453 to be used in process modeling, specifying whether the system is to use the state at time t and the dynamics to predict an approximation for the state after one millisecond, three seconds, twelve hours, etc., without examining states in between.

using the dynamic map in conjunction with the first, second and third data sets to perform a simulation of the transfer of material or information between entities;

For example, when the Map runs a simulation, it instructs each Shipper to obey that Shipper's internal algorithm concerning the state of its internal variable and the messages it sends to other Shippers about content levels and quantities to be

transferred to the Shippers. It is the Map's responsibility to maintain synchrony among the different sub-processes.

6) outputting the simulation results

The results of the simulation may be displayed in a number of different formats, including, for example, graphs of selected variables with respect to time, 2D or 3D phase diagrams jointly showing motion of selected variables, colored shapes attached to Shippers, etc.

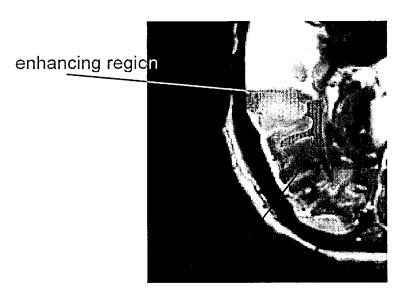
The features of claim 1 will now be related to the above-referenced example (i.e., the presentation of metastasis routes), wherein numbers in parenthesis correspond to the above-numbered claim elements.

- (1) The entities between which material (primary brain cancer cells) is transferred can be (i) the site of initial occurrence, or, if the invention is being used on a patient in whom the primary brain tumor has already recurred, the site of recurrence, and (ii) distal sites of possible recurrence such as the junction of the radiating fibers of the corpus callosum with the gray matter in the brain hemisphere opposite to the first site.
- (2) The channels connecting the entities, for example, can be the major directional white matter tracts through the genu of the corpus callosum and onto the tracts in the other hemisphere. More precisely, it is the extracellular spaces (outside the axonal tracts) along these fibers that can constitute the channels connecting the entities.

- (3) For simplicity, the types of material or information that each entity transfers via each channel can be the primary tumor cells. In a more comprehensive look, the cytokines, serum proteins etc. can also be included as types of material.
- (4) The dynamic map can comprise the probability of recurrence of primary tumor cell mass with time. The tumor cells will occupy mostly select niches and require time for their migration to distal sites. This time will depend on many variables that can be displayed according the software architecture in accordance with the invention.

 These variables included what may be called channel capacity and flow and so on. Fig. ii (below) provides a static view of a purely thresholded look at such a dynamic map.

 The region marked "cancer cell spread" can be further color coded for relative probabilities of occurrence and annotated with anatomical marks to indicate the regions of the brain which may then be evaluated for consideration of prophylactic surgery etc.



B. Rejections under 35 U.S.C. § 102(e)

Claims 1-5, 7-11, 13-21, 23-38 and 41 stand rejected under 35 U.S.C. § 102(e) as being anticipated by *Allen*. Reversal of the rejection is respectfully requested for at least the following reasons.

1) Claims 1 and 41

a) Allen Does Not Disclose the Step of Creating a Dynamic Map

Claim 1 recites, *inter alia*, creating a dynamic map that includes a <u>list of active</u>

entities (e.g., active Shippers IDs), wherein the dynamic map is <u>communicatively</u>

coupled to the active entities so as to provide information thereto (e.g., the dynamic

map informs each active Shipper of the other active Shippers with which it is in contact).

In the final Office Action, the Examiner, citing to Fig. 15 of *Allen*, contends that a

dynamic map is disclosed. Further, the Examiner also contends that Fig. 15 shows a

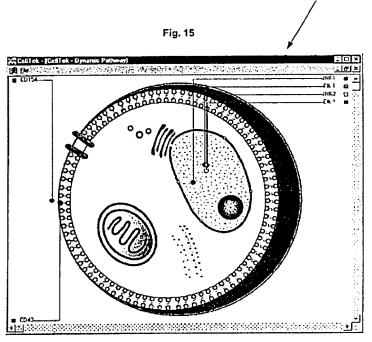
list of active entities (upper right corner of Fig. 15).¹ In the Advisory Action, the

Examiner further states that columns 1-3 (through line 16) of *Allen* broadly teach using
the dynamic map (possible cellular

biochemical pathways).2

Referring initially to Fig. 15 of Allen (reproduced at right), there is shown a graphical display that includes a circular object with several shapes inside the object.

Textual information is shown in the upper right hand corner, and lines



¹ See the Examiner's remarks on page 4, item d of the final Office Action

² Page 2 of the Advisory Action

are drawn from the textual information to the objects. A header of Fig. 15 is labeled "Dynamic Pathway".

The textual information in the upper right corner (i.e., the alleged active entities) appears to be abbreviations, although no explanation of these abbreviations is provided in Fig. 15 (presumably they refer to proteins). Further, no explanation is provided in Fig. 15 of what the objects shown therein represent. Standing alone, it is not seen how Fig. 15 shows a map <u>communicatively coupled</u> to active entities, as recited in claim 1.

Moving now to the specification, *Allen* has been found to refer to Fig. 15 in one location, i.e., column 21, lines 13-15. In this portion, *Allen* only discloses that Fig. 15 shows a preferred dynamic display of pathways. No mention is made with regard to the text in the upper right hand corner, nor are any pathways expressly identified.

Moreover, no mention is made that the abbreviations in the upper right corner of Fig. 15 pertain to active entities (a word search of *Allen* shows that Elk1, Elk2, JNK1 and JNK2 are not discussed therein).

In view of the above, one cannot reasonably conclude that Fig. 15 and the disclosure of *Allen* describe creating a dynamic map that includes a list of <u>active</u> entities, wherein the dynamic map is <u>communicatively coupled to the active entities so</u> as to provide information thereto, as recited in claim 1.

Moving now to the Examiner's contention as set forth in the Advisory Action that columns 1-3 (through line 16) broadly teach creating a dynamic map as recited in claim 1, Applicants respectfully disagree. While the cited portion does refer to simulating biochemical pathways, no mention is found that these biochemical pathways include a list of active entities, or that the dynamic map is communicatively coupled to the active

entities so as to provide information thereto, as recited in claim 1. Thus, the cited portion of *Allen* has not been shown to teach this feature of claim 1.

b) The Data Sets

i) Allen Has Not Been Shown to Disclose a First Data Set of Entities

Claim 1 recites <u>creating</u> a first data set of entities between which material or information is transferred (e.g., a data set of Shippers). In the Final Office Action, the Examiner contends that the elements, physical interactions and pathways as described in column 3, lines 46-47 of *Allen* disclose this feature.³ The cited portion of *Allen* is reproduced below.

Cellular pathways involve molecular physical interactions between elements in series (typically, though not exclusively, proteins) leading to an outcome in a cellular process.

As is evident from the cited portion, nowhere is it stated that a <u>data set</u> is created that includes <u>entities between which information is transferred</u>. This portion merely describes a cellular process that occurs between elements in a pathway. Nothing is said or even suggested with regard to creating a data set of entities as recited in claim 1.

Further, in the Advisory Action the Examiner contends that the entities are inherent in the pathway. In support of showing the entities are inherent in a pathway, the Examiner provides as an example a "start point" and an "end point" of the pathway⁴

³ Page 4 of the final Office Action

⁴ Page 2, item 1a) of the Advisory Action

(this position is completely different from the Examiner's contention in the final Office Action that Elk1, Elk2, JNK1 and JNK2 as shown in Fig. 15 are entities). While a pathway may be said as having a start point and an end point, they still are merely points (e.g., points on a line, points in space, etc.). It is not seen how a point on a pathway pertains to an entity (e.g., a shipper) as recited in claim 1.

Moreover, even if the Examiner's contention is accepted, *Allen* makes no mention of creating a <u>data set</u> of start points and end points. *Allen* merely refers to a method for simulating cellular biochemical pathways, without referencing a data set of start points or end points of the pathway.

In view of the above, *Allen* has not been shown to disclose creating a first data set of entities between which information is transferred, as recited in claim 1.

ii) Allen Has Not Been Shown to Disclose a Second Data Set of Channels Connecting the Entities

Claim 1 also recites creating a second data set of channels connecting the entities (e.g., contacts). In the final Office Action, the Examiner contends that the "pathways" as disclosed in *Allen* are channels.⁵ Assuming the pathways are channels, *Allen* still has not been shown to disclose this feature of claim 1. In particular, as discussed above *Allen* has not been shown to disclose creating a data set of entities as recited in claim 1. Absent such entities, *Allen* also cannot teach creating a second data set of channels connecting the entities.

⁵ Page 4 of the final Office Action

In the Advisory Action, the Examiner further contends that the channels are inherent in the pathways. This contention is discussed below in section a.

a) The Examiner Has Not Met the Burden of Establishing Inherency

In the Advisory Action, the Examiner takes the position that entities between which material or information is transferred (as recited in claim 1) and channels connecting the entities (as recited in claim 1) are inherent features of a selected pathway. In support of showing inherency for the first data set, the Examiner provides as an example a start point and an end point of a pathway. With respect to the channels, the Examiner does not provide any support showing that channels connecting the entities are inherent features of the pathways.⁶

In showing inherency it is the Examiner's burden to provide rationale or evidence tending to show inherency. Specifically, § 2112 of the MPEP provides the following:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' "In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)

⁶ See page 2 of the Advisory Action

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Regarding the first data set of entities, it is respectfully submitted that the Examiner provides no basis in fact or technical reasoning showing how an "entity" as recited in claim 1 is an inherent feature of a pathway. A start point and an end point are merely points in space, and not entities (e.g., shippers). While a pathway may have a start point and an end point as stated by the Examiner, the Examiner does not discuss how an "entity", such as a shipper, and a "point" in space are related. Thus, the Examiner has not established that entities between which material or information is transferred, as recited in claim 1, are an inherent feature of a pathway.

Regarding the second data set, the Examiner provides <u>no</u> reasoning or basis in fact on how a pathway includes channels connecting the entities. Thus, the Examiner also has not established inherency for the second data set.

For at least the above reasons, the Examiner has not met his burden of showing inherency and, thus, the rejection is improper.

iii) Allen Does Not Disclose a Third Data Set of Types of Materials or Information Transferred by Each Entity

Claim 1 also recites creating a third data set of types of material or information that each entity transfers via each channel (e.g., Cargo that is received and/or transmitted by Shippers). In the Final Office Action, the Examiner implies this feature reads on a "physical interaction". As used in *Allen*, physical interactions is understood

⁷ Page 4 of the final Office Action

to describe how cellular materials interact to achieve an outcome.⁸ A physical interaction, however, does not describe a <u>type</u> of material or information that each entity <u>transfers</u> via each channel. Thus, the rejection as set forth in the final Office Action does not show how *Allen* teaches this feature of claim 1.

In the Advisory Action, the Examiner, citing to column 1, lines 45-48 of *Allen*, further states that the types of material that each entity transfers via each channel reads on a protein that "travels" in a potential pathway.⁹ The cited portion of *Allen* is reproduced below.

One aspect of the invention relates to the prediction of (a) functional properties of a protein, (b) potential interaction partners of the protein, and/or (c) potential target biochemical pathways within which the protein may interact. Thus, according to the invention, the influence of a given stimulus on a biochemical pathway can be assessed.

As is evident from the cited text, the invention of *Allen* is directed to predicting functional properties of the protein, interaction partners of the protein, and potential pathways within which the protein may interact. Nothing is said in the cited text with respect to creating a data set of <u>types of material or information that each entity</u> transfers via each channel.

Moreover, nothing is said in the cited text with respect to proteins being transferred by the start and end points of the pathways (i.e., the alleged entities). As best understood, the cited portion says nothing with respect to the proteins being "transferred" through the pathways.

⁸ See column 4, lines 6-9 of *Allen*

⁹ Page 2 of the Advisory Action

Allen simply has not been shown to teach creating a third data set of types of material or information that each entity transfers via each channel, as recited in claim 1.

c) Allen Does Not Disclose Using the Dynamic Map in Conjunction with the First, Second and Third Data Sets to Perform a Simulation

Claim 1 also recites using the dynamic map in conjunction with the first, second, and third data sets (e.g., data sets of Shippers, Contacts and Cargos) to perform a simulation of the transfer of material or information between entities. In the Final Office Action the Examiner asserts that Fig. 1A teaches using the dynamic map as set forth in claim 1.¹⁰ Applicants respectfully disagree with the Examiner's interpretation of Fig. 1A.

Prior to discussing Fig. 1A relative to the above-referenced feature of claim 1, it is beneficial to review the Examiner's contentions regarding claim 1 and *Allen*. In particular, the Examiner contends the following:

- the "elements" as recited in column 3, line 47 teaches the first data set of entities;
- ii) the "pathways" as recited in column 3, line 46 teaches the second data set of channels;
- the "physical interaction" as recited at column 3, line 46 teaches the third data set of types of materials; and
- iv) the "dynamic pathway" as shown in Fig. 15 teaches the dynamic map. 11

¹⁰ Page 4, item e of the final Office Action

¹¹See page 4 of the final Office Action

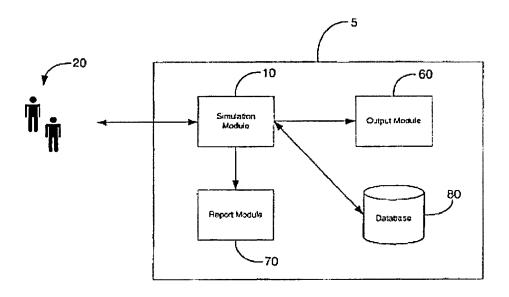


Fig. 1A

Moving now to Fig. 1A of *Allen*, which is reproduced above, there is shown a high level block diagram of the major modules of the system described in *Allen*, one of which is a simulation module 10. On its face, Fig. 1A says *nothing* with respect to using the "elements" (i.e., the alleged first data set of entities), "pathways" (i.e., the alleged second data set of channels), "physical interaction" (i.e., the alleged third data set of types of materials) *and* "dynamic pathway" (i.e., the alleged dynamic map) to perform a simulation. Fig. 1A simply shows that a simulation module is present in the system of *Allen*, and that the simulation module interfaces with a report module 70, a database 80 and an output module 60. Other than Fig. 1A, the Examiner does not identify in the final Office Action other parts of *Allen* that teach a simulation as recited above.

Moreover, the undersigned has reviewed *Allen* and could not find any teaching that the simulation module 10 of Fig. 1A performs a simulation using the "elements",

"pathways", "physical interaction" <u>and</u> "dynamic pathway" as alleged by the Examiner.

Thus in the final Office Action, *Allen* has not been shown to teach using the dynamic map in conjunction with the first, second, and third data sets to perform a simulation of the transfer of material or information between entities as recited in claim 1.

In the Advisory Action, the Examiner further states that *Allen* broadly teaches in light of columns 1, 2 and 3 (to line 16) using the possible cellular biochemical pathways (the alleged dynamic map) in conjunction with the alleged first, second and third data sets to perform a simulation (e.g., simulating pathways). While *Allen* does disclose simulating cellular biochemical pathways, *Allen* has not been found to disclose such pathways are simulated using:

- i) a dynamic map that includes a list of active entities in conjunction with
- ii) a first data set of entities between which material or information is transferred,
- iii) a second data set of channels connecting the entities, and
- vi) a third data set of types of materials or information that each entity transfers via each channel.

As is evident from the above, *Allen* simply has not been shown to teach all the features of claim 1 and, therefore, the rejection must be reversed. Further, the remaining art to *Bard*, *Le Pennec* and *Priem* has not been found to make up for the deficiencies of *Allen* and, thus, claim 1 also has not been shown to be obvious in view of *Allen*, *Bard*, *Le Pennec* and *Priem*. Similar comments apply to claim 41 and, thus, the rejection of claim 41 also must be reversed.

2. Claim 14

Claim 14 depends from claim 13 and indirectly depends from claim 1 and thus the above comments are applicable to claim 14. Claim 14 further recites that the at least one spatially distributed object contains a numerical description of the condition of the at least one spatially distributed object, wherein the numerical description comprises lesions of medically recognized types in a tissue represented by the at least one spatially distributed object.

In rejecting claims 13 and 14, the Examiner identifies the "elapsed time" as shown in Fig. 11 as a numerical description of the condition of the at least one spatially distributed object, and then states the numerical description comprises diseases (a lesion).¹² It is not seen how the elapsed time in Fig. 11 can be transformed into information regarding a disease, as contended by the Examiner. Elapsed time does not comprise a lesion in a tissue.

3. Claim 16

Claim 16 depends from claim 1 and thus the above comments are applicable to claim 16. Claim 16 further recites that a signal passed between a first spatially distributed object and a second spatially distributed object depends upon the internal state of the first spatially distributed object and the second spatially distributed object, and upon an algorithmic specification characterizing the transfer capacity between the first spatially distributed object and the second spatially distributed object.

In rejecting claim 16, the Examiner points to JNK1 of Fig. 15 as teaching the feature wherein a signal passed between a first spatially distributed object and a

¹² Page 5, last two paragraphs of the final Office Action

second spatially distributed object depends upon the internal state of the first and second spatially distributed objects.

Initially, it is noted that in rejecting claim 1 (discussed above) the Examiner relied on JNK1 as an example of an active entity.¹³ Now in claim 16 (which depends from claim 1), JNK1 is relied upon as an internal state of an object. Clearly, the same element cannot be used to show two different features of a claim.

Moreover, the specification of *Allen*, as discussed above, makes no reference to JNK1. Thus, without more, one cannot reasonably conclude that JNK1 of Fig. 15 represents an <u>internal state of a spatially distributed object</u>, as recited in claim 1. This is particularly true in light of the conventional use of "JNK1", which is typically used to refer to a type of type of protein (clearly not a state of a spatially distributed object).

In view of the above, *Allen* has not been shown to teach all the features of claim 16 and, thus, reversal of the rejection of claim 16 is also respectfully requested.

C. Rejections Under 35 U.S.C. § 103(a)

Claims 6, 12 and 22 stand rejected under 35 USC § 103(a) as being unpatentable over *Allen* in view of *Bard*, *Le Pennec et al.* and/or *Priem*. Claims 6, 12 and 22 depend from claim 1 and thus these claims are novel over *Allen* for at least the reasons set forth above. Further, and as noted above, neither *Bard*, *Le Pennec et al.* nor *Priem* have been found to make up for the deficiencies of *Allen*. Thus, reversal of the rejection of claims 6, 12 and 22 is also requested.

¹³ See page 4, item d) of the final Office Action

In view of the foregoing, it is respectfully submitted that the claims are patentable over the applied art and that the rejections advance by the Examiner should be reversed.

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, L.L.P.

/Kenneth W. Fafrak/

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Claims Appendix

1. A computer-implemented method of dynamically modeling and displaying a passage of material or information between at least two spatially distributed objects in a body, comprising:

creating a first data set of entities between which material or information is transferred; creating a second data set of channels connecting the entities;

creating a third data set of types of material or information that each entity transfers via each channel;

creating a dynamic map that includes a list of active entities, wherein the dynamic map is communicatively coupled to the active entities so as to provide information thereto;

using the dynamic map in conjunction with the first, second, and third data sets to perform a simulation of the transfer of material or information between entities; and outputting the simulation results.

- 2. The method of claim 1, wherein at least one spatially distributed object represents at least one of a group selected from: a tissue of the body; and an organ of the body.
- 3. The method of claim 1, wherein at least one spatially distributed object represents a device used for medical intervention.
- 4. The method of claim 1, wherein at least one spatially distributed object represents a material introduced into the body by accident.
- 5. The method of claim 1, wherein at least one spatially distributed object represents material introduced into the body by an aggressor.
- 6. The method of claim 1, wherein at least one spatially distributed object represents material introduced into the body for cosmetic purposes.

- 7. The method of claim 1, wherein at least one spatially distributed object is represented as having a spatial form and points of contact with other objects.
- 8. The method of claim 7, wherein at least one spatially distributed object has a geometrical description of a three-dimensional form.
- 9. The method of claim 8, wherein the three-dimensional form comprises a polygonal surface representing a spatial boundary.
- 10. The method of claim 8, wherein the three-dimensional form comprises a specification of points in a grid laid out in three-dimensional space.
- 11. The method of claim 7, wherein at least one spatially distributed object has a geometrical description of a two-dimensional surface.
- 12. The method of claim 7, wherein at least one spatially distributed object has a geometrical description of a one-dimensional curve.
- 13. The method of claim 1, wherein at least one spatially distributed object contains a numerical description of the condition of the at least one spatially distributed object.
- 14. The method of claim 13, wherein the numerical description comprises lesions of medically recognized types in a tissue represented by the at least one spatially distributed object.
- 15. The method of claim 13, wherein the numerical description may refer to the states at particular spatial locations within the at least one spatially distributed object.
- 16. The method of claim 1, wherein a signal passed between a first spatially distributed object and a second spatially distributed object depends upon the internal

state of the first spatially distributed object and the second spatially distributed object, and upon an algorithmic specification characterizing the transfer capacity between the first spatially distributed object and the second spatially distributed object.

- 17. The method of claim 16, wherein the algorithmic specification is provided with a digital implementation of the method.
- 18. The method of claim 16, wherein the algorithmic specification is obtained by a user and connected to a digital implementation of the method by programming means.
- 19. The method of claim 1, wherein at least one spatially distributed object and at least one algorithm governing an internal state of the at least one spatially distributed object are provided with a digital implementation of the method.
- 20. The method of claim 1, wherein a subset of the at least one spatially distributed object, at least one algorithm governing the evolution of an internal state of the at least one spatially distributed object, and at least one passed signal are constructed by the user and connected to a digital implementation of the method by programming means provided with the digital implementation of the method.
- 21. The method of claim 1, wherein at least one spatially distributed object is grouped as a different spatially distributed object, and at least one algorithm associated with the different spatially distributed object is run on data associated with the different spatially distributed object to approximate the effect of the at least one algorithm on the data associated with the at least one spatially distributed objects.
- 22. The method of claim 1, wherein a geometrical description is modified by a global transformation specifying a correspondence between a reference coordinate space of the method and a coordinate space appropriate to a particular subject.

- 23. The method of claim 1, wherein a geometrical description may be modified individually to better match a corresponding entity in a particular subject to create a new hypothetical example.
- 24. The method of claim 1, further comprising: specifying the condition of at least one spatially distributed object; running at least one associated algorithm; and reporting the results.
- 25. The method of claim 1, further comprising: specifying an initial condition of at least one spatially distributed object; running at least one associated algorithm while continuing to intervene in the state of the at least one spatially distributed object in real-time; and observing results.
- 26. The method of claim 1, further comprising: running at least one associated algorithm on a system that resides on a central server; and having a user issue modification and simulation commands over the Internet which are executed on the central server.
- 27. The method of claim 1, further comprising: having a user obtain standard system data; and having the user issue modification and simulation commands that are executed on a computer.
- 28. The method of claim 27, further comprising displaying a three-dimensional graphical image representing a spatial arrangement of at least one spatially distributed object.
- 29. The method of claim 28, where the three-dimensional graphical image is color-coded.
 - 30. The method of claim 27, further comprising displaying results as numbers.

- 31. The method of claim 24, where a second program issues modification and simulation commands and receives data describing the results of system computations as input for further computations by said second program.
- 32. The method of claim 1, wherein the information comprises at least one of a group consisting of: material; and signals.
- 33. The method of claim 1, wherein the library data set further maintains interaction types and characteristic times for each interaction type.
- 34. The method of claim 1, further comprising enabling a user to input initial conditions for the entities between which material or information is transferred, and wherein performing the simulation includes using the initial conditions as part of the simulation.
- 35. The method of claim 1, further comprising enabling a user to input variations of the data sets.
- 36. The method of claim 1, further comprising creating a data set of the response of each entity to material or information received via each channel.
- 37. The method of claim 36, wherein creating a data set of the response includes transfer of the same or other material or information to other entities via said channels.
- 38. The method of claim 1, further comprising creating a data set of the transmission characteristics of each channel for each type of material or information that the said channel can carry.
- 41. A computer program embodied on a computer readable medium for dynamically modeling and displaying a passage of material or information between at least two spatially distributed objects in a body, comprising:

code that creates a first data set of entities between which material or information is transferred;

code that creates a second data set of channels connecting the entities; code that creates a third data set of types of material or information that each entity transfers via each channel;

code that creates a dynamic map that includes a list of active entities, wherein the dynamic map is communicatively coupled to the active entities so as to provide information thereto;

code that uses the dynamic map in conjunction with the first, second, and third data sets to perform a simulation of the transfer of material or information between entities; and

code that outputs the simulation results.

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